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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Duane G. Krzysik, et al.                      Art Unit 1615  
Serial No. 10/659,967  
Filed        September 11, 2003  
Confirmation No. 5034  
For    SKIN CARE TOPICAL OINTMENT  
Examiner Humera N. Sheikh

July 13, 2007

SUBSTITUTE APPEAL BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES.....	ii
I. REAL PARTY IN INTEREST.....	1
II. RELATED APPEALS AND INTERFERENCES.....	1
III. STATUS OF CLAIMS.....	2
IV. STATUS OF AMENDMENTS.....	2
V. SUMMARY OF CLAIMED SUBJECT MATTER.....	2
VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.....	5
VII. ARGUMENT.....	5
Claims 1, 3, 5-13, 15-23, 25, and 27 are patentable under 35 U.S.C. §103(a) over EP 0497144 in view of Morrison and further in view of Grollier et al.....	5
Claims 1, 3, 5-13, 15-23, and 25 are patentable under 35 U.S.C. §103(a) over Krzysik et al. in view of EP 0497144 .	16
Claims 1, 3, 5-6, 10-13, and 19-22 are patentable under 35 U.S.C. §103(a) over Krzysik et al. in view of EP 0497144.	20
VIII. CONCLUSION.....	23
CLAIMS APPENDIX.....	24
EVIDENCE APPENDIX.....	33
RELATED PROCEEDINGS APPENDIX.....	33

## TABLE OF AUTHORITIES

### REFERENCES

West Group, <u>Manual of Patent Examining Procedure</u> , 8th Ed. Rev. Two (2004).....	7, 12, 13, 16, 20
Chung et al. (EP 0497144B1), Jan. 15, 1992.....	7

### CASES

Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06- 1402 (Fed. Cir., May 9, 2007).....	8
KSR International Co. v. Teleflex Inc., et al., 550 U.S. _____, 2007 WL 1237837 (2007) .....	8, 12, 13
In re Mill, 916 F.2d 680.....	12
Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902.....	14

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**APPEAL BRIEF**

This is a substitute appeal brief submitted to correct the Status of Claims as requested in the Notice of Non-Compliant Appeal Brief mailed June 14, 2007. The original appeal, which was submitted May 10, 2007, was from the final rejection of the claims of the above-identified application made in the Office action dated November 30, 2006. A Notice of Appeal was submitted via electronic filing on March 12, 2007.

**I. REAL PARTY IN INTEREST**

The real party in interest in connection with the present appeal is Kimberly-Clark Worldwide, Inc. of 401 N. Lake Street, Neenah, Wisconsin 54957-0349, a corporation of the state of Delaware, owner of a 100 percent interest in the pending application.

**II. RELATED APPEALS AND INTERFERENCES**

Appellants are aware of one pending appeal, which may be related to, directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal. Specifically, there is a pending appeal in the related case of U.S. Application No. 10/660,319 (filed on September 11, 2003).

### **III. STATUS OF CLAIMS**

Claims 1, 3, 5-13, 15-23, 25, and 27 are currently pending in the application. Claims 2, 4, 14, 24, and 26 have been cancelled. A copy of the pending claims appears in the Claims Appendix of this Brief.

Claims 1, 3, 5-13, 15-18, 21, and 27 stand rejected under 35 U.S.C. §103(a). The rejection of claims 1, 3, 5-13, 15-18, 21, and 27 under 35 U.S.C. §103(a) is being appealed.

Claims 1, 3, 5-13, 15-23, and 25 stand rejected under 35 U.S.C. §103(a). The rejection of claims 1, 3, 5-13, 15-23, and 25 under 35 U.S.C. §103(a) is being appealed.

Claims 1, 3, 5-6, 10-13, and 19-22 stand rejected under 35 U.S.C. §103(a). The rejection of claims 1, 3, 5-6, 10-13, and 19-22 under 35 U.S.C. §103(a) is being appealed.

### **IV. STATUS OF AMENDMENTS**

No amendments have been filed after the final rejection.

### **V. SUMMARY OF CLAIMED SUBJECT MATTER**

The following summary correlates claim elements to specific embodiments described in the application specification, but does not in any manner limit claim interpretation. Rather, the following summary is provided only to facilitate the Board's understanding of the subject matter of this appeal.

Diaper rash and related skin ailments are common forms of skin irritation and inflammation of those parts of an infant's

or adult's body normally covered by an absorbent product such as a diaper or incontinence product.<sup>1</sup> Although conventional topical ointments have been somewhat satisfactory in combating such skin ailments, many of the ointments do not spread easily or evenly across the skin surface, and may feel greasy or gritty upon application to the skin. The present disclosure is directed to providing a topical ointment for direct application to the skin for preventing and treating diaper dermatitis and related rashes and skin ailments. Specifically, the topical ointment comprises various rheology enhancers that have been found to improve the spreadability of the ointment across the surface of the skin, and provide enhanced aesthetics of the ointment.<sup>2</sup>

In one specific embodiment, as set forth in independent claim 1, the present invention is directed to a topical ointment comprising from about 30% by total weight of the ointment to about 80% by total weight of the ointment of an emollient<sup>3</sup>, from about 20% by total weight of the ointment to about 40% by total weight of the ointment of a structurant<sup>4</sup>, and from about 0.1% by total weight of the ointment to about 40% by total weight of the ointment of a rheology enhancer<sup>5</sup>. The rheology enhancer is selected from the group consisting of polyisobutylene; hydrogenated polyisobutene and butylene/ethylene/styrene copolymers; hydrogenated polyisobutene and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isononyl isononanoate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isododecane and

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<sup>1</sup> Specification at page 1, paragraph 2.

<sup>2</sup> See Specification at page 5, paragraph 15 and page 9, paragraph 26.

<sup>3</sup> Specification at page 6, paragraph 20.

<sup>4</sup> Specification at page 8, paragraph 24.

ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isohexadecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isopropyl palmitate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; and combinations thereof.<sup>6</sup>

In another specific embodiment, as set forth in independent claim 23, the topical ointment comprises from about 30% by total weight of the ointment to about 80% by total weight of the ointment of an emollient, from about 20% by total weight of the ointment to about 40% by total weight of the ointment of a structurant, from about 0.1% by total weight of the ointment to about 40% by total weight of the ointment of a rheology enhancer, from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a particulate material<sup>7</sup>, and from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a low HLB surfactant<sup>8</sup>. The rheology enhancer is selected from the group consisting of polyisobutylene; hydrogenated polyisobutene and butylene/ethylene/styrene copolymers; hydrogenated polyisobutene and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isononyl isononanoate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isododecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isohexadecane and ethylene/propylene/styrene copolymers and

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<sup>5</sup> Specification at page 10, paragraph 27.

<sup>6</sup> Specification at page 10, paragraph 28.

<sup>7</sup> Specification at page 11, paragraph 31.

<sup>8</sup> Specification at page 12, paragraph 33.

butylene/ethylene/styrene copolymers; isopropyl palmitate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; and combinations thereof.

**VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

The claims 1, 3, 5-13, 15-18, 21, and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0497144 ('144) in view of Morrison (U.S. 6,340,467) and further in view of Grollier et al. (U.S. 4,925,653).

The claims 1, 3, 5-13, 15-23, and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Krzysik et al. (U.S. 6,149,934) in view of EP 0497144 ('144).

The claims 1, 3, 5-6, 10-13, and 19-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Krzysik et al. (U.S. 6,287,581) in view of EP 0497144 ('144).

**VII. ARGUMENT**

**Rejection of Claims 1, 3, 5-13, 15-18, 21, and 27 under 35 U.S.C. §103(a)**

Claims 1, 3, 5-13, 15-18, 21, and 27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0497144 ('144) in view of Morrison (U.S. 6,340,467) and further in view of Grollier et al. (U.S. 4,925,653).

Claim 1 is directed to a topical ointment comprising from about 30% by total weight of the ointment to about 80% by total weight of the ointment of an emollient, from about 20% by total weight of the ointment to about 40% by total weight of the ointment of a structurant, and from about 0.1% by total weight



of the ointment to about 40% by total weight of the ointment of a rheology enhancer. The rheology enhancer is selected from the group consisting of polyisobutylene; hydrogenated polyisobutene and butylene/ethylene/styrene copolymers; hydrogenated polyisobutene and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isononyl isononanoate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isododecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isohexadecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isopropyl palmitate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; and combinations thereof.

The '144 reference discloses cosmetic compositions comprising a particulate styrene-ethylene-propylene copolymer; an emollient selected from the group consisting of isododecane, a C<sub>9</sub>-C<sub>12</sub> aliphatic hydrocarbon, a C<sub>9</sub>-C<sub>12</sub> isoparaffin, a mineral oil, isotetracosane, an ester made from a C<sub>3</sub>-C<sub>12</sub> alcohol and a C<sub>3</sub>-C<sub>18</sub> carboxylic acid, and mixtures thereof; and a third component selected from the group consisting of a colorant, a sunblock agent, and mixtures thereof. The particulate styrene-ethylene-propylene copolymer is present in the composition in an amount of from 0.5% by weight to 90% by weight, and more preferably, from 1.0% by weight to 25% by weight. The emollient is present in the composition in an amount of from 10% by weight to 90% by weight, and more preferably, from 10% by weight to 70% by weight. If the third component includes a colorant, the colorant is present in the composition in an amount of from 1.0% by weight to 85% by weight, and more preferably, from 5% by weight to 50% by weight. If a sunblock

agent is present in the composition, the sunblock agent is present in the composition in an amount of from 0.50% by weight to 90% by weight.

Significantly, the '144 reference fails to disclose any of the specific rheology enhancers as required by claim 1. At best, the rheology enhancers disclosed in the '144 reference include isododecane in combination with styrene-ethylene-propylene diblock copolymers<sup>9</sup>. As noted above, however, in Applicants' claim 1, when the rheology enhancer includes isododecane, the isododecane is used in combination with triblock ethylene/propylene/styrene copolymers and triblock butylene/ethylene/styrene copolymers. No where in the '144 reference is the use of triblock ethylene/propylene/styrene copolymers or any butylene/ethylene/styrene copolymers taught or suggested.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate

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<sup>9</sup> EP 0497144B1 at page 2, lines 25-27. The Office refers to the styrene-ethylene-propylene diblock copolymers of '144 as being the same or equivalent to the ethylene/propylene/styrene triblock copolymers used as rheology enhancers in Applicants' claim 1. As discussed more fully herein, it should be noted that Applicants' assert that this is not accurate; specifically, the diblock copolymers in '144 are not equivalent to the triblock copolymers used in Applicants' claim 1.

why some combinations would have been obvious where others would not.<sup>10</sup> The Office has clearly failed to meet its burden under numbers (1) and (2) above, as the cited references, alone or in combination, have not taught or suggested all of the claimed limitations of Applicants' claim 1, and further, there is no apparent reason for one skilled in the art to modify and/or combine the references to arrive at Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

As noted above, '144 fails to teach or suggest the specific rheology enhancers as required by claim 1. The Office states that Example 2 of the '144 reference, which discloses the admixture of isododecane with a styrene-ethylene-propylene diblock copolymer, is one of the rheology enhancers claimed in Applicants' claim 1. With all due respect, Applicants' assert that Example 2 (or any other Example in the reference) fails to disclose any of the specific rheology enhancers required in claim 1. Specifically, while '144 discloses combining isododecane with the diblock styrene-ethylene-propylene copolymer, no where in '144 is it taught or suggested to use the combination of isododecane with the **triblock** ethylene/propylene/styrene copolymers, and **triblock** butylene/ethylene/styrene copolymers as a rheology enhancer in its cosmetic composition.

In the Advisory action dated March 2, 2007, the Office further states that Applicants' argument that the '144 reference teaches diblock copolymers rather than the triblock copolymers of instant claim 1 is not persuasive since

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<sup>10</sup> Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) See also KSR Int'l Co. v. Teleflex, Inc., et al. 550 US \_\_\_\_, 2007 WL 1237837 at 12 (2007).

Applicants have not demonstrated any superior results through the inclusion of triblock copolymers in their topical ointment. Applicants respectfully disagree. As discussed in the Letter To Patent And Trademark Office In Response To Final Office Action filed on January 30, 2007, and again below, the triblock copolymers as required in Applicants' instant claim 1 provide improved functional properties to the topical ointment that cannot be achieved with the diblock copolymers of the '144 reference. As discussed below, the inclusion of triblock copolymers allow for the desired spreadability and transfer; characteristics that are not easily achieved with these types of products.

Specifically, in Applicants' claimed invention, triblock copolymers are surprisingly superior rheology enhancers as these copolymers produce a gelled or film-forming composition, allowing the composition to **easily transfer** from an absorbent article such as a diaper to form a film-like barrier layer on the skin, thereby protecting the skin from water and moisture, which can cause diaper rash and irritation. Diblock copolymers (such as the styrene-ethylene-propylene copolymers, available as Kraton 1701X, of the '144 reference) are not effective in forming a film-like barrier as diblock copolymers are produced in chains of polymers. A gelled or film-like network is substantially more difficult to produce as compared to the grid-like matrix formed by the copolymers of the '144 reference. As such, the styrene-ethylene-propylene diblock copolymers of '144 are not functionally equivalent to the ethylene/propylene/styrene triblock copolymers useful as rheology enhancers in Applicants' claim 1.

Furthermore, to produce the composition as disclosed in the '144 reference, the styrene-ethylene-propylene copolymer is mixed with an emollient to form a transparent, uniform, preliminary dispersion of copolymer. The copolymer is not dissolved, but is formed into a dispersion of copolymer (i.e., containing solid particulates); the copolymer will not gel to perform like the rheology enhancers of the instantly claimed invention; that is, the copolymer will not allow the composition to form into a gelled or film-forming barrier on the skin's surface.

The Morrison and Grollier et al. references fail to overcome the above shortcomings. Specifically, Morrison discloses a solid or semi-solid hydrocarbon gel for use as an ointment, balm, or salve to treat wounds, burns, or injuries to the skin. The hydrocarbon gel comprises from greater than about 0% to about 99% by weight solid or semi-solid hydrocarbon and from greater than about 0% to about 50% by weight of at least one block copolymer selected from the group consisting of a triblock copolymer; a radial block copolymer; a multi-block copolymer; a diblock copolymer; and mixtures of these polymers. Suitable hydrocarbons for use in the hydrocarbon gel include paraffin wax, petrolatum, synthetic waxes, mineral waxes, vegetable oil waxes, polyethylene waxes, microcrystalline waxes, natural waxes such as carnauba, beeswax, and the like.<sup>11</sup> Suitable block copolymers include rubber-type polymers consisting of styrene monomer units and rubber monomer units, and/or comonomer units; diblock styrene polymers such as styrene-ethylenepropylene, styrene-ethylenebutylene, styrene-butadiene, and styrene-isoprene; and triblock styrene polymers

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<sup>11</sup> U.S. 6,340,467 at column 2, lines 26-30.

such as styrene/ethylene/butadiene/styrene, styrene/butadiene/styrene, and styrene/isoprene/styrene.<sup>12</sup>

Optionally, a liquid hydrocarbon, such as white mineral oil, can be included in the hydrocarbon gel of Morrison in an amount ranging from about 5% to 75% by weight.<sup>13</sup> Additionally, when the hydrocarbon gel is a solid hydrocarbon gel, the gel may optionally include from about 0.1% to about 50% by weight additional ingredients such as various waxes. Examples of the various waxes include carnauba wax, beeswax, or candellia wax.<sup>14</sup>

Grollier et al. disclose a sunscreen composition containing at least one oil-soluble agent absorbing UV rays and at least one polyisobutylene. The polyisobutylene has a viscosity-average molecular weight of between 8,000 and 65,000 at ambient temperature. The sunscreen composition can optionally comprise fatty substances such as mineral, animal or vegetable oils or waxes, fatty acids, fatty acid esters such as triglycerides of fatty acids containing from 6 to 12 carbon atoms, fatty alcohols and oxyethylenated fatty alcohols, water, monoalcohols or lower polyalcohols containing from 1 to 6 carbon atoms, or an aqueous alcohol solution. The sunscreen compositions have a higher protection index than that of conventional sunscreen compositions which contain only liposoluble UV screens.

No where in the cited references is it disclosed to use isododecane in combination with ethylene/propylene/styrene copolymers, and butylene/ethylene/styrene copolymers in the compositions of either the Morrison or Grollier et al. references. Moreover, no where in these cited references is

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<sup>12</sup> *Id.* at column 3, lines 17-62.

<sup>13</sup> *Id.* at column 2, lines 46-51.

there any disclosure of the use of isododecane as a rheology enhancer.

In addition to the disclosure of isododecane as a rheology enhancer, the Office states in the Office action dated April 24, 2006 and, again in the final Office action dated November 30, 2006, that the combination of cited references further discloses each and every limitation of claim 1 using the polyisobutylene disclosed in Grollier et al. as the rheology enhancer. Specifically, the Office states that Grollier et al. disclose that the addition of polyisobutylene to a skin care composition has the advantage of protecting human epidermis against UV radiation, and as such, one skilled in the art would be motivated to use the polyisobutylene in the cosmetic composition of '144.

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some motivation or suggestion, either in the references themselves or in knowledge generally available to one skilled in the art, to combine the references and arrive at the claimed subject matter.<sup>15</sup> The mere fact that the references can be combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. In re Mill, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). As recently set forth by the Supreme Court in KSR

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<sup>14</sup> *Id.* at column 4, lines 34-38.

<sup>15</sup> As further set forth in M.P.E.P. §2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the reference itself, or in the knowledge generally available to one or ordinary skill in the art. This standard has been upheld by the Supreme Court in KSR

International Co. v. Teleflex, Inc., et al., the reason to combine the elements of the prior art in the claimed fashion must be apparent to one skilled in the art.<sup>16</sup> A close reading of the cited references clearly indicates that the combination of claimed elements would not have been apparent to one skilled in the art without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing).<sup>17</sup>

As noted above, the Office states that one skilled in the art would be motivated to combine the polyisobutylene of Grollier et al. with the '144 and Morrison references simply because Grollier et al. disclose that the addition of polyisobutylene to a skin care composition has the advantage of protecting human epidermis against UV radiation. This generic statement, without anything further, is not sufficient motivation for one skilled in the art, at the time Applicants' invention was made, to combine the cited references and arrive at Applicants' invention. Specifically, providing a sunblock agent to protect the skin from sunburns is merely an optional ingredient in the '144 reference. In the Final Office action, the Office states that although the sunblock agent is an optional ingredient in the '144 reference, 'optional' is a positive suggestion that cannot be ignored in the art. While

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International Co. v. Teleflex, Inc., et al., 550 U.S.\_\_\_\_, 2007 WL 1237837 at 14 (2007)

<sup>16</sup> See, 550 U.S.\_\_\_\_, 2007 WL 1237837 at 12 (2007).

<sup>17</sup> M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts



Applicants agree that the teaching of the optional sunblock agent cannot be ignored, this disclosure alone does not provide sufficient motivation or apparent reason for one skilled in the art to use the polyisobutylene of the Grollier et al. reference as the sunscreen agent in the '144 reference.

Specifically, if a sunblock agent is optionally added for use in the cosmetic composition of '144, the '144 reference provides numerous suitable sunblock agents. Specifically, on page 2, lines 30-32, the '144 reference discloses preferred sunblock agents such as melanin, melanin protein, submicron particles of titanium dioxide and iron oxide, octyl methoxycinnamate, benzophenone-3, and mixtures thereof. As such, why would one skilled in the art, reading the '144 reference, be motivated to use a sunblock agent in addition to those cited as suitable agents in the '144 reference? Furthermore, why would one skilled in the art, reading the '144 reference, be motivated to specifically use the polyisobutylene of the Grollier et al. reference over those listed as suitable sunblock agents in '144? One skilled in the art simply would not, and could not, be so motivated. Additionally, there are a myriad of sunblock agents in the art, many of which could be suitable for use in the cosmetic compositions of '144. What is important is that there is no apparent reason to use the specific polyisobutylene sunblock agent of Grollier et al. in the cosmetic compositions of '144 over any of the other enormous number of sunblock agents described in the art.

Additionally, while polyisobutylene is disclosed in the Grollier et al. reference, the Grollier et al. reference fails to disclose the polyisobutylene in its composition in

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gleaned from the prior art. Grain Processing Corp. v. American-Maize-

combination with a structurant being present in the composition in an amount of from about 20% by total weight to about 40% by total weight as required in Applicants' claim 1. Specifically, the only amounts of structurant disclosed in the reference are in the working Examples, and the Examples show structurant amounts of at most 15.6%.<sup>18</sup> As such, none of the cited references disclose any of the specific rheology enhancers in combination with an emollient and structurant in the amounts required of the ointment of Applicants' claim 1.

Moreover, Morrison fails to provide any suggestion or motivation to use the polyisobutylene of Grollier et al. in its composition or in the cosmetic composition of '144. Specifically, Morrison is directed to hydrocarbon gels containing medicinal ingredients useful as an ointment, balm, or salve for wounds. No where in Morrison is the purpose of protecting the skin from UV radiation even suggested.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the '144, Morrison, and Grollier et al. references. There is simply no suggestion or motivation to do so provided in the references themselves or in the knowledge of one skilled in the art as required for a *prima facie* case of obviousness under M.P.E.P. §2143. As such, claim 1 is patentable over '144 in view of Morrison and further in view of Grollier et al.

Claims 3, 5-13, 15-18, 21, and 27 depend directly or indirectly from claim 1. As such, claims 3, 5-13, 15-18, 21,

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Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

<sup>18</sup> See U.S. 4,925,653 Examples 1-8, disclosing structurants in the amounts of 6.8% (Example 1), 6% (Example 2), 7.2% (Example 3), 0% (Example 4), 7% (Example 5), 15.6% (Example 6), 4.6% (Example 7), and 0% (Example 8).

and 27 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

**Rejection of claims 1, 3, 5-13, 15-23, and 25 under 35 U.S.C. §103(a).**

Claims 1, 3, 5-13, 15-23, and 25 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Krzysik et al. (U.S. 6,149,934) in view of EP 0497144 ('144).

Amended claim 1 is discussed above.

U.S. 6,149,934 ('934) discloses an absorbent article having a bodyside liner that includes a lotion formulation for reducing the abrasion of the skin caused by the liner and for improving skin health. The lotion formulation comprises from about 5 to about 95 weight percent of an emollient, from about 5 to about 95 weight percent of a wax, and, optionally, from about 0.1 to about 25 weight percent of a viscosity enhancer.

As noted by the Office, the '934 reference fails to teach or suggest the rheology enhancers as required in Applicants' claim 1. In an attempt to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness, the Office cites the '144 reference for combination with '934.

The '144 reference is discussed above.

As noted above, in order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of

ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. As further noted above, this is not a rigid formula as the common sense of those skilled in the art can demonstrate why some combination would have been obvious where others would not. The Office has clearly failed to meet its burden under numbers (1) and/or (2) above, as the cited references, alone or in combination, have not taught or suggested all of the claimed limitations of Applicants' claim 1 and, further, there is no apparent reason for one skilled in the art to combine the cited references to arrive at Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

As noted above, '934 fails to teach or suggest each and every limitation of claim 1. Specifically, no where in the '934 reference is it taught or suggested to use the rheology enhancers of claim 1 in the lotion formulation of '934. At best, the suitable viscosity enhancers disclosed in the '934 reference include polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, polyethylene, silica, talc, colloidal silicone dioxide, zinc stearate, cetyl hydroxyl ethyl cellulose and other modified celluloses, and the like, and mixtures thereof.<sup>19</sup>

The '144 reference fails to overcome the above shortcomings. As noted above, the '144 reference fails to teach or suggest the rheology enhancers required in claim 1. Specifically, while the '144 reference discloses the use of isododecane in combination with diblock styrene-ethylene-propylene copolymers, no where in the '144 reference is it

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<sup>19</sup> U.S. 6,149,934 at column 10, lines 57-62.

taught to combine isododecane with triblock ethylene/propylene/styrene copolymers, and triblock butylene/ethylene/styrene copolymers as required in the topical ointments of Applicants' claim 1. As such, neither of the cited references disclose each and every limitation required by claim 1.

Furthermore, the combination of elements from the '934 and '144 references would not have been apparent to one skilled in the art. More particularly, a close reading of the '934 reference actually teaches away from using the styrene-ethylene-propylene copolymers of '144 in the '934 lotion formulation. Specifically, as disclosed in the '934 reference, it is desirable that the formulation of the '934 reference, as with the ointment of the instant invention, is **transferable** from an absorbent article such as a diaper to the skin to provide improved skin health. As disclosed in the '934 reference, the lotion formulation desirably can be applied to the bodyside liner such that, in use, the lotion formulation transfers to the skin reducing friction and thus irritation.<sup>20</sup> Additionally, it is desirable that the lotion formulation transfers to the skin to improve skin health.<sup>21</sup> As such, why would one skilled in the art, reading the '934 reference, choose to use the styrene-ethylene-propylene copolymers of '144, which are disclosed as providing a **transfer proof** composition, in the lotion formulation of the '934, designed to transfer from the absorbent article to the skin? Common sense simply would not, and could not, so incline one skilled in the art to make this combination. Furthermore, the Office states in the final Office action mailed November 30, 2006 that one

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<sup>20</sup> See U.S. 6,149,934 at column 1, lines 48-53.

<sup>21</sup> See *id* at Abstract and column 3, lines 48-58.

advantage of the styrene-ethylene-propylene copolymer is that it would cause the '934 formulation to be transfer proof and, as such, the formulation would not flake-off the skin. While it may be true that once on the skin, being transfer proof is an advantage, the lotion formulation of '934 (as well as the ointment of the instantly claimed invention) must be capable of easily transferring from an absorbent article to the skin to provide the desired skin benefits. As such, a transfer proof composition, such as provided in the '144 reference, would not be desirable for use in the formulation of the '934 reference (or in the ointment of the instantly claimed invention). As neither of the references alone, or in combination, disclose each and every element of Applicants' claim 1 and, further, there is no apparent reason to combine the references to arrive at Applicants' claim 1, claim 1 is patentable over the cited references.

Claims 3, 5-13, and 15-22 depend directly or indirectly from claim 1. As such, claims 3, 5-13, and 15-22 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 23 is similar to claim 1 and further requires the topical ointment to comprise from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a particulate material, and from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a low HLB surfactant. Claim 23 is patentable for the same reasons as claim 1 set forth above, as well as for the additional elements it requires. Furthermore, claim 25, which directly depends from claim 23, is patentable for the same

reasons as claim 23 set forth above, as well as for the additional elements it requires.

**Rejection of claims 1, 3, 5-6, 10-13, and 19-22 under 35 U.S.C. §103(a) .**

Claims 1, 3, 5-6, 10-13, and 19-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Krzysik et al. (U.S. 6,287,581) in view of EP 0497144 ('144) .

Claim 1 is discussed above.

U.S. 6,287,581 ('581) discloses a skin barrier enhancing body side liner on an absorbent article comprising a lipid-enriched hydrophobic composition. The lipid-enriched hydrophobic composition comprises from about 0.1 to about 95 weight percent natural fats or oils, from about 0.1 to about 10 weight percent sterols and sterol derivatives, from about 0.5 to about 20 weight percent of humectant, from about 1 to about 20 weight percent of water-in-oil emulsifying surfactant/surfactant combination having an HLB range from about 3 to about 6, from about 5 to about 95 weight percent emollient, from about 5 to about 95 weight percent wax, and from about 1 to about 25 weight percent viscosity enhancer.

As noted by the Office, the '581 reference fails to teach or suggest the rheology enhancers as required in claim 1. In an attempt to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness, the Office cites '144 for combination with '581. Applicants again assert that the Office has failed to meet its burden to satisfy a *prima facie* case of obviousness, as the cited references, alone or in combination, have not taught or

suggested all of the claimed limitations of Applicants' claim 1, nor is it apparent to one skilled in the art to combine the references to arrive at each and every limitation of Applicants' claim 1.

The '144 reference is discussed above.

As noted above, '581 fails to teach or suggest each and every limitation of claim 1. Specifically, nowhere in the '581 reference is it taught or suggested to use the rheology enhancers of claim 1 in the lipid-enriched hydrophobic composition of '581. At best, the suitable viscosity enhancers disclosed in the '581 reference include polyolefin resins, polyolefin polymers, ethylene/vinyl acetate copolymers, polyethylene, and the like, and mixtures thereof.<sup>22</sup>

The '144 reference fails to overcome the above shortcomings. As noted above, the '144 reference fails to teach or suggest the rheology enhancers required in claim 1. As such, neither of the cited references discloses each and every limitation required by claim 1.

Furthermore, even if the cited references disclose each and every limitation of Applicants' claim 1 (which, as discussed above, Applicants assert that they do not), one skilled in the art would not have reason to combine the cited references to arrive at Applicants' claim 1. Specifically, like the '934 lotion formulation, the lotion of '581 is designed to transfer from an absorbent article to the skin to improve skin health.<sup>23</sup> As such, one skilled in the art, reading the '581 reference, would not, and could not, reasonably use the styrene-ethylene-propylene copolymers of the '144

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<sup>22</sup> U.S. 6,287,581 at column 10, lines 25-29.

<sup>23</sup> See *id* at column 2, lines 32-42.



composition, which cause the composition to be transfer proof, in the lotion of '581, which desirably can be transferred from the absorbent article to the skin to improve skin health. As neither reference discloses each and every limitation of Applicants' claim 1 and, further, there is no motivation or apparent reason to combine the cited references, claim 1 is patentable over the cited references.

Claims 3, 5-6, 10-13, and 19-22 depend directly or indirectly from claim 1. As such, claims 3, 5-6, 10-13, and 19-22 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

**VIII. Conclusion**

The Office has failed to establish a *prima facie* case of obviousness pursuant to 35 U.S.C. § 103, because the Office has failed to show a reference that teaches each and every element of Applicants' claims, and furthermore, there is no apparent reason for one skilled in the art to modify and/or combine the cited references to arrive at each and every element of claims 1, 3, 5-13, 15-23, 25, and 27. For these reasons, and for those more fully stated above, Appellants respectfully request the Office's rejections be reversed and claims 1, 3, 5-13, 15-23, 25, and 27 be allowed.

The Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 19-1345.

Respectfully submitted,

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**CLAIMS APPENDIX**

1. A topical ointment comprising from about 30% by total weight of the ointment to about 80% by total weight of the ointment of an emollient, from about 20% by total weight of the ointment to about 40% by total weight of the ointment of a structurant, and from about 0.1% by total weight of the ointment to about 40% by total weight of the ointment of a rheology enhancer, wherein the rheology enhancer is selected from the group consisting of polyisobutylene; hydrogenated polyisobutene and butylene/ethylene/styrene copolymers; hydrogenated polyisobutene and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isononyl isononanoate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isododecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isohexadecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isopropyl palmitate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; and combinations thereof.

3. The topical ointment as set forth in claim 1 wherein the emollient is present in an amount of from about 60% by total weight of the ointment to about 80% by total weight of the ointment.

5. The topical ointment as set forth in claim 1 wherein the rheology enhancer is present in an amount of from about 0.5% by total weight of the ointment to about 30% by total weight of the ointment.

6. The topical ointment as set forth in claim 1 wherein the rheology enhancer is present in an amount of from about 1% by total weight of the ointment to about 25% by total weight of the ointment.

7. The topical ointment as set forth in claim 1 wherein the ointment has a process temperature viscosity of from about 50 cPs to about 50,000 cPs.

8. The topical ointment as set forth in claim 1 wherein the ointment has a process temperature viscosity of from about 75 cPs to about 10,000 cPs.

9. The topical ointment as set forth in claim 1 wherein the topical ointment has a process temperature viscosity of from about 80 cPs to about 5,000 cPs.

10. The topical ointment as set forth in claim 1 wherein the ointment further comprises an additional ingredient selected from the group consisting of antifoaming agents, antimicrobial actives, antiviral actives, antifungal actives, antiseptic actives, antioxidants, cosmetic astringents, drug astringents, biological additives, colorants, deodorants, film formers, fragrances, lubricants, natural moisturizing agents, skin conditioning agents, skin exfoliating agents, skin protectants, solvents, hydrophilic surfactants, and UV absorbers.

11. The topical ointment as set forth in claim 1 wherein the emollient is selected from the group consisting of petrolatum, mineral oil, mineral jelly, isoparaffins, vegetable oils, avocado oil, borage oil, canola oil, castor oil, chamomile, coconut oil, corn oil, cottonseed oil, evening primrose oil, safflower oil, sunflower oil, soybean oil, sweet almond, and the like, lanolin, partially hydrogenated vegetable oils, sterols and derivatives, polydimethylsiloxanes,

methicone, cyclomethicone, dimethicone, dimethiconol, trimethicone, organo-siloxanes, silicone elastomer, gums, resins, fatty acid esters, esters of C<sub>6</sub>-C<sub>28</sub> fatty acids, and C<sub>6</sub>-C<sub>28</sub> fatty alcohols, glyceryl esters and derivatives, fatty acid ester ethoxylates, alkyl ethoxylates, C<sub>12</sub>-C<sub>28</sub> fatty alcohols, C<sub>12</sub>-C<sub>28</sub> fatty acids, C<sub>12</sub>-C<sub>28</sub> fatty alcohol ethers, Guerbet alcohols, Guerbet Acids, Guerbet Esters, and combinations thereof.

12. The topical ointment as set forth in claim 1 wherein the structurant has a melting point of from about 45°C to about 85°C.

13. The topical ointment as set forth in claim 1 wherein the structurant is selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, polymers, bayberry wax, beeswax, stearyl dimethicone, stearyl trimethicone, C<sub>20</sub>-C<sub>22</sub> dimethicone, C<sub>20</sub>-C<sub>22</sub> trimethicone, C<sub>24</sub>-C<sub>28</sub> dimethicone, C<sub>20</sub>-C<sub>22</sub> trimethicone, C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, stearyl benzoate, behenyl benzoate, esparto, hydrogenated cottonseed oil, hydrogenated jojoba oil, hydrogenated jojoba wax, hydrogenated microcrystalline wax, hydrogenated rice bran wax,

japan wax, jojoba buffer, jojoba esters, jojoba wax, lanolin wax, microcrystalline wax, mink wax, motan acide wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, synthetic spermaceti wax, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, synthetic jojoba wax, C<sub>14</sub>-C<sub>28</sub> fatty acid ethoxylates and C<sub>14</sub>-C<sub>28</sub> fatty ethers, C<sub>14</sub>-C<sub>28</sub> fatty alcohols, C<sub>14</sub>-C<sub>28</sub> fatty acids, polyethylene, oxidized polyethylene, ethylene-alpha olefin copolymers, ethylene homopolymers, C<sub>18</sub>-C<sub>45</sub> olefins, poly alpha olefins, hydrogenated vegetable oils, polyhydroxy fatty acid esters, polyhydroxy fatty acid amides, ethoxylated fatty alcohols and esters of C<sub>12</sub>-C<sub>28</sub> fatty acids, and C<sub>12</sub>-C<sub>28</sub> fatty alcohols, and combinations thereof.

15. The topical ointment as set forth in claim 1 further comprising from about 0.1% by total weight of the ointment to about 25% by total weight of the ointment of a particulate material.

16. The topical ointment as set forth in claim 15 wherein the particulate material is present in an amount of from about

0.1% by total weight of the ointment to about 10% by total weight of the ointment.

17. The topical ointment as set forth in claim 15 wherein the particulate material is selected from the group consisting of talc, mica, titanated mica, iron oxide titanated mica, magnesium carbonate, calcium carbonate, magnesium silicate, spherical silica, hydrated silica, silica beads, titanium dioxide, zinc oxide, nylon powder, polyethylene powder, ethylene acrylates copolymer powder, methacrylate powder, polystyrene powder, silk powder, crystalline cellulose, starch, bismuth oxychloride, guanine, kaolin, bentonite, hectorite, laponite, chalk, diatomaceous earth, microsponges, microcapsules, boron nitride, and combinations thereof.

18. The topical ointment as set forth in claim 15 wherein the particulate material is selected from the group consisting of talc, polyethylene, hydrated silica, kaolin, bentonite, hectorite, laponite, titanium dioxide, titanated mica, microsponges, microcapsules, and mixtures thereof.

19. The topical ointment as set forth in claim 1 further comprising from about 0.1% by total weight of the ointment to



about 10% by total weight of the ointment of a surfactant having an HLB in the range of from about 2 to about 7.

20. The topical ointment as set forth in claim 19 wherein the surfactant is selected from the group consisting of sorbitan monooleate, sorbitan sequioleate, sorbitan trioleate, glyceryl stearate, sorbitan stearate, sorbitan tristearate, and mixtures thereof.

21. The topical ointment as set forth in claim 19 further comprising from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a hydrophilic skin care active.

22. The topical ointment as set forth in claim 21 wherein the hydrophilic skin care active is selected from the group consisting of botanicals, glycerin, hydrogenated starch hydrolysate, propylene glycol, sodium PCA, sodium lactate, sorbitol, and mixtures thereof.

23. A topical ointment comprising from about 30% by total weight of the ointment to about 80% by total weight of the ointment of an emollient, from about 20% by total weight of the

ointment to about 40% by total weight of the ointment of a structurant, from about 0.1% by total weight of the ointment to about 40% by total weight of the ointment of a rheology enhancer, from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a particulate material, and from about 0.1% by total weight of the ointment to about 10% by total weight of the ointment of a low HLB surfactant, wherein the rheology enhancer is selected from the group consisting of polyisobutylene; hydrogenated polyisobutene and butylene/ethylene/styrene copolymers; hydrogenated polyisobutene and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isononyl isononanoate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isododecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isohexadecane and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; isopropyl palmitate and ethylene/propylene/styrene copolymers and butylene/ethylene/styrene copolymers; and combinations thereof.

25. The topical ointment as set forth in claim 23 wherein the rheology enhancer is polyisobutylene.

27. The topical ointment as set forth in claim 1 wherein the rheology enhancer is polyisobutylene.

**EVIDENCE APPENDIX**

Applicants rely on the EP 0497144B1 reference to support the above arguments. The earlier counterpart of EP 0497144B1, EP 0497144A1, was cited in the Office action received in the instant case on April 24, 2006. Furthermore, Applicants relied on EP 0497144B1 in the Response to Final Office Action submitted January 30, 2007. The EP 0497144B1 reference was considered by the Office on March 2, 2007 in the Advisory Action. Applicants enclose herewith copies of the EP 0497144B1 reference.

**RELATED PROCEEDINGS APPENDIX**

None.